## 4.5 FDA-Regulated Interventions



***Guidelines***

1. *Required if the study will utilize an FDA-regulated intervention*
2. ***Format:***
	1. *No page limit*
	2. *Margins min. 0.5”*
	3. *NIH-recommended fonts:* Arial, Georgia, Helvetica, Palatino Linotype
3. ***Content:***
	1. *Describe availability of study agents and support for the acquisition and administration of study agent(s)*
	2. *Indicate IND/IDE status of study agent, if applicable, and whether investigators have had interactions with the FDA*
	3. *If study agent currently has an IND/IDE number, provide that information.*
	4. ***Note:*** *The awarding component may request consultation with the FDA and the IND/IDE sponsor about the proposed clinical trial after peer review and prior to award*
	5. *Contact* *ctsiora@mednet.ucla.edu* *for additional guidance*
4. *When form is complete:*
	1. *Remove this box*
	2. *Save file as “4.5 FDA-Regulated Interventions”*